

Serial No. 09/626,127

Amendment Dated July 14, 2003

Reply To Office Action Of Mach 12, 2003

### REMARKS/ARGUMENTS

By the above amendments, claim 2 has been amended, recently introduced claims 3-8 have been renumbered as claims 64-69, as set forth in the Office Action, the dependency of claims 66 and 68 has been amended to correspond to the correct numbering of claims 64-69, and new claims 70-90 have been added. Therefore, claims 2 and 64-90 are currently under consideration.

### OBJECTIONS

In the Office Action, the claims were objected to for improper numbering. Applicant had not considered the numbering of previously canceled claims when new claims 3-8 were introduced in the papers submitted on January 30, 2003. Accordingly, Applicant has renumbered new claims 3-8 as claims 64-69, as indicated in the Office Action. The dependency of claims 66 and 68 has also been corrected to correspond to the renumbered claims.

### CLAIM REJECTIONS: 35 USC § 102

In the Office Action, claims 2 and 64 were rejected under 35 USC § 102 as allegedly being anticipated by Jaynes et al. (US 5,597,945). Applicant has amended claim 2 to recite that the recombinant expression construct encodes a "mammalian lysosomal enzyme".

The Jaynes et al. reference discloses a genetically modified plant that has been altered to express insect enzymes, such as an antimicrobial peptide. Column 7, lines 15-16 of Jaynes et al., states that the antimicrobial genes are "derived from insect hemolymph, such as attacin"

The Jaynes et al. reference neither suggests nor discloses a construct that encodes a mammalian lysosomal enzyme. A person of ordinary skill in the art would not be motivated to use a construct that encodes mammalian lysosomal enzyme with the Jaynes teachings, which

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The Jaynes et al. reference neither discloses nor suggests a construct that encodes a mammalian lysosomal enzyme. Applicant therefore respectfully asserts that the present invention, as recited in amended claim 2, is clearly distinguished over the prior art and that claim 2 is now in condition for allowance.

CLAIM REJECTIONS: 35 USC § 103, Jaynes & Overbeeke

In the Office Action, claims 2, 64, 67 and 68 were rejected under 35 USC § 103 as allegedly being obvious over the combined disclosures of Jaynes et al. and Overbeeke et al. (US 5,082,778). As mentioned above, Applicant has amended claim 2 to recite that the recombinant expression construct encodes a "mammalian lysosomal enzyme".

Jaynes et al., teaches encoding of an insect enzyme, as discussed above, for the purpose of enhancing disease resistance of the modified plant. Overbeeke et al. teaches use of a gene that encodes an enzyme from guar seed. The teachings of Jaynes et al. and Overbeeke et al. either taken alone or in combination with one another neither suggests nor discloses a recombinant expression construct that encodes a "mammalian lysosomal enzyme".

Further, Overbeeke et al. teaches away from expression of human lysosomal enzymes at column 1, lines 24-28 where it states:

During the investigations resulting in the present invention, it was found that the *S. carlsbergensis* enzyme and the *E. coli* enzyme were not suited for the specific use described below. Human alpha-galactosidase could not be tested owing to lack of availability, but, in view of the experiments described below (cf Example 4 and the Table in this specification), it is very likely that this human enzyme is also not suited for the specific use.

Clearly, the Overbeeke et al. reference teaches away from the expression of a mammalian lysosomal enzyme. A person of ordinary skill in the art would not be motivated to combine

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2 for several reasons. First, Jaynes uses an insect gene to enhance disease resistance of a plant. Second, Overbeeke teaches encoding of guar seed enzymes. Third, Overbeeke teaches away from expression of mammalian enzymes. The combination of these two disclosures neither suggests nor discloses a construct that encodes a mammalian lysosomal enzyme, as recited in amended claim 2. For this reason and others, Applicant respectfully asserts that amended claim 2 and dependent claims 64, 67 and 68 are not obvious over the prior art and are now in condition for allowance.

CLAIM REJECTIONS: 35 USC § 102(e) and/or 103, Jaynes et al.

In the Office Action, claims 2 and 64-69 were rejected under 35 USC § 102(e) or in the alternative, under 35 USC § 103 as allegedly being obvious over the disclosure of Jaynes et al. As mentioned above, Applicant has amended claim 2 to recite that the recombinant expression construct encodes a "mammalian lysosomal enzyme".

Jaynes et al., teaches encoding of an insect enzyme, as discussed above. Jaynes neither suggests nor discloses a construct that expresses mammalian enzymes. Applicant respectfully asserts that amended claim 2 clearly distinguishes over the Jaynes et al. reference and is now in condition for allowance.

Further, the Jaynes et al. reference teaches genetically modified plant for the purpose of improving disease resistance of the modified plant. The present invention, on the other hand, is not a genetically modified plant, but rather is a recombinant expression construct that is for the purpose of encoding a mammalian lysosomal enzyme in large quantities for pharmaceutical applications in humans. There is no teaching or suggestion in the Jaynes et al. disclosure that would motivate a person of ordinary skill in the art to make a construct for encoding a mammalian lysosomal enzyme. Applicant respectfully asserts that this rejection is unwarranted in light of the teachings of Jaynes et al. and the amendment to claim 2, which specifies that the

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Applicant respectfully asserts that claims 2 and 64-69 are now in condition for allowance.

### NEW CLAIMS

New claims 70-90 have been introduced to further define the invention. Applicant respectfully asserts that no new issues are raised by introduction of these claims since these new claims include further limitations in addition to those considered by the Examiner in claim 2. Specifically, the new claims are directed to methods and constructs that include the use of a recombinant expression construct that includes a nucleotide sequence encoding a lysosomal enzyme and a promoter that regulates the expression of the nucleotide sequence in a plant cell.

New claims 71-90 are specifically drawn to methods of making a lysosomal enzyme, by a method that uses a recombinant (+) sense single stranded RNA plant viral vector.

In the Preliminary Amendment Under 37 CFR § 1.607 Copying Claims from Patent For Purposes of Interference, filed July 26, 2000, Applicant specifically pointed out the similarities between the claimed subject matter of the instant application and the allowed claims in Radin et al., US Patent number 5,929,304 (hereinafter "Radin et al.").

Radin et al., claims a method for producing lysosomal enzymes in which a "transgenic plant cell or plant is transformed or transfected . . . ." (see claim 1, lines 5-6). Radin et al. also mentions "transfection of plant cells or tissues with appropriately engineered plant viruses" (see column 16, lines 33-34). However, Radin et al. provides no teaching or enablement as to what viruses or how they might be engineered or used. Further, the Examiner who issued Radin et al. appears to have limited her reasons for allowance to expression and recovery from transgenic plants and cells. Accordingly, Applicant believes that new claims 71-90 of the instant application are distinguished from the claims of Radin et al.

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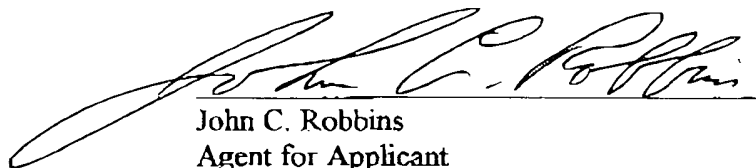
PRIORITY CLAIM

Applicant previously established a priority claim extending back to several related patent applications filed the late 1980s. Applicant wishes to point out that a construct encoding mammalian lysosomal enzyme, such as human lipase, is disclosed in Example 18, at page 66 of US SN 07/363,138, filed June 8, 1989, to which the present application claims priority. A copy of the originally filed patent specification of SN 07/363,138 was previously provided to the Examiner.

Applicant respectfully asserts that the application is now in condition

Thank you. If you have any questions, please feel free to contact the undersigned.

Respectfully submitted,



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